core Rx®

# DEVELOPMENT AT OUR CORE

**EXPERTISE**
**SPEED**
**RESULTS**

[SOLID]

[LIQUID]

[SEMI-SOLID]

# WE PROVIDE SCIENTIFIC SOLUTIONS TO YOUR DRUG PRODUCT DEVELOPMENT CHALLENGES

CoreRx, a contract development and manufacturing organization with a focus on clinical phase drug product development, offering state of the art facilities to support your supply chain needs throughout the entire clinical trial process. Our integrated offerings provide comprehensive services for the development, manufacturing and testing of solid, liquid and semi-solid dosage forms.

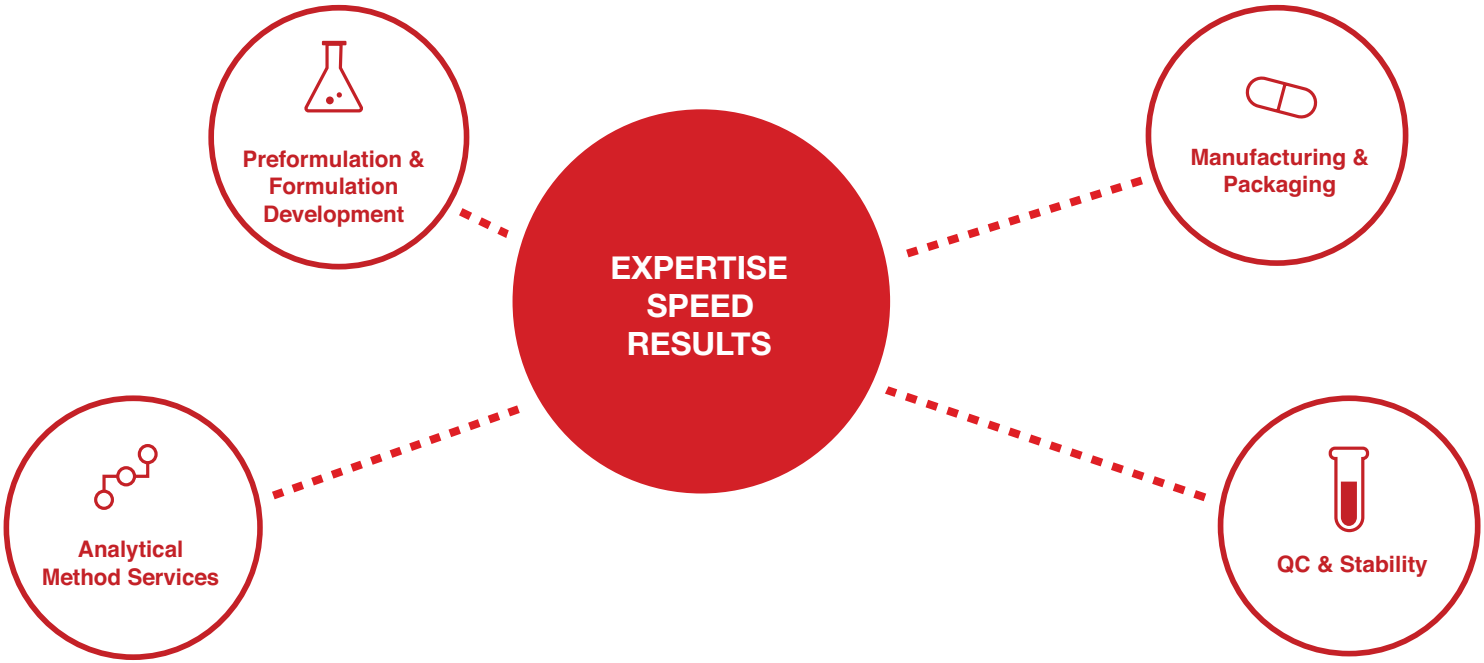
The art of drug product development is at the core of what we do. Our staff combines years of pharmaceutical development expertise to produce safe, effective, and innovative drug products, on time, and on budget. We differentiate ourselves by mixing highly experienced scientists with a wide range of technologies to deliver optimal solutions to meet our clients' needs. From simple formulations to complex, modified release dosage forms, CoreRx's solutions maximize client investments, shorten development time and reduce overall costs.


**www.corerxpharma.com**

# OUR SERVICES

CoreRx offers **comprehensive drug product development and manufacturing** services to the pharmaceutical and biotechnology industries. Supporting virtual, mid-size, and multinational companies, we provide novel formulation development solutions, customized clinical material, manufacturing and packaging solutions, and related analytical and stability support services.

From first-in-man studies to late phase manufacturing support, CoreRx provides years of **pharmaceutical development expertise** to produce safe, effective, and innovative drug products, on time, and on budget.




# PREFORMULATION SERVICES AND SUPPORT

Characterization of the Active Pharmaceutical Ingredient (API) is critical to designing a successful formulation approach. CoreRx can evaluate the characteristics of your API, control particle size, conduct small scale studies to understand key parameters around solubility and stability, and perform excipient compatibility studies to identify the right ingredients to enhance API performance across a variety of dosage forms.

## Preformulation Services Include:

- API Physical & Chemical Characterization
- Particle Size Analysis
- Polymorphism Screening
- pH/Stability/Solubility Profiles
- Partition Coefficient
- Thermal Analysis
- Hygroscopicity Evaluation
- Excipient Compatibility Testing

## Particle Size Control & Reduction Technologies:

**Dry Process**

- Jet Mill
  - Particle size range of 1 – 45 microns

**Wet Process**

- Microfluidization
  - Particle size reduction for submicron and nano-sized particles
- Proprietary MicroJetReactor *(MJR®)* Nanosizer
  - Extreme particle size reduction for nano-sized particles down to 100nm

# FORMULATION DEVELOPMENT

Our robust experience and capabilities in formulation development covers a wide range of dosage forms and delivery technologies. Keeping goals and objectives in mind, we focus on creating formulations designed to meet our clients' needs.  From early phase formulations for preclinical research through QBD evaluations, CoreRx can support your formulation needs for any phase of development.

## Formulation Technologies

### Solid Dosage Forms

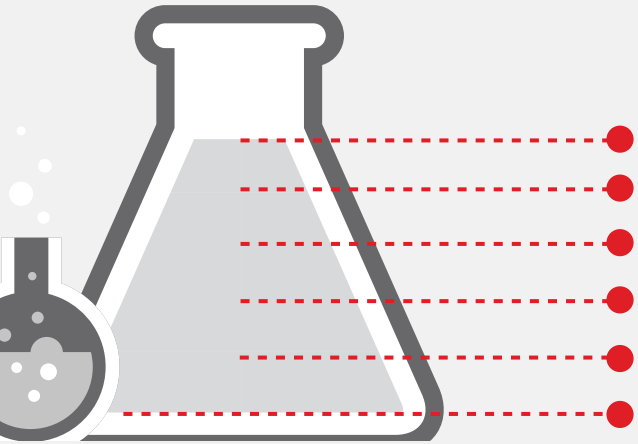
Blending
Dry Granulation
Roller Compaction
Wet Granulation
Fluid Bed Drying
Spray Drying
Extrusion/Spheronization
Encapsulation
Tableting Including
*- (Micro and Multi-Layer)*
Pan Coating/Drying

### Liquid & Semi-Solid Dosage Forms

Mixing
Homogenization
Filling
Lyophilization

## Overcoming Formulation Challenges

Developing formulations is as much an art as it is a science, and it's the people that make the difference. Our formulation team consists of PhD and Master level formulators and chemists that we would stack up against any in the Industry.



**From these experts, we provide guidance and support across the following areas:**

- Taste Masking/Flavoring
- Creating Modified/Controlled Release Delivery of API
- Creating Fixed Dose Combination Products
- Solubilizing Water-Insoluble Drugs
- Stabilizing Unstable Molecules
- Enhancing Bioavailability

## Formulation Testing and Evaluation

- Product Potency & Uniformity Evaluation
- Chemical & Physical Stability Evaluations
- In-Vitro Release & Permeability Testing
- Photostability Studies
- Temperature Cycling & Freeze-Thaw Studies
- Material/Packaging Compatibility Testing

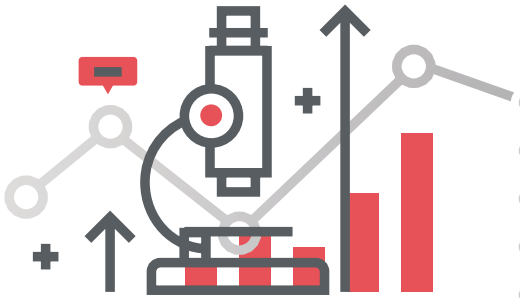
**"We will supply the right ingredients to ensure your product reaches its maximum potential."**

# ANALYTICAL AND STABILITY

Drug product development and clinical manufacturing efforts at CoreRx are fully supported by our GMP compliant in-house analytical laboratories. Equipped with state of the art analytical instruments, CoreRx provides analytical method support, release and stability testing services for a variety of dosage forms including: oral, parenteral, ophthalmic, suppository, and topical routes of delivery.

## Method Development & Validation

CoreRx provides method development, optimization, transfer, and phase appropriate qualification/validation services for a variety of dosage forms.



### Our Services Include:

- HPLC & UPLC Assay & Related Substance Methods
- Single Point, Multi-Point and Two-stage Dissolution Methods
- Franz Cell Permeability Assay Methods
- GC Assay Methods for Organic Impurities
- Cleaning Methods for Support of GMP Manufacturing

## Drug Product Release & ICH Stability Services

CoreRx offers comprehensive drug product release & stability services as either stand-alone projects, or in support of full development and manufacturing programs conducted at CoreRx.

### Our QC Services Include:

- Release Testing & Certificate of Analysis
- Stability Protocol Generation
- Stability Storage
- Stability Testing
- Stability Summary Report Generation
- Stability Time Points and Conditions
- Ad Hoc Report Generation

### GMP Stability Chambers:

**Walk-In Chambers**

- 5°C
- 25°C/60% RH
- 30°C/65% RH
- 40°C/75% RH

**Reach-In Chambers**

- Three Custom Condition Chambers
- Darwin Freeze/Thaw Chamber

# MANUFACTURING

CoreRx offers diversified technical resources, capacity, flexibility, and experience to manufacture with strict quality compliance. Our manufacturing capabilities include a variety of dosage forms, with the scale to support phase I – niche commercial manufacturing. Our facility design, licenses, and controls allow CoreRx to provide manufacturing services for DEA schedule II - V substances as well as high potency compounds.

## Tablets

- Immediate to Modified Release
- Orally Disintegrating (ODT)
- Multi-Layer Tablets
- Micro-Tablets
- Multi-API Combination Products

## Liquid Oral Dosage Forms

- Solutions
- Suspensions
- Emulsions
- Syrups

## Coating

**Experience coating with:**

- Functional Excipients
- Non-Functional Excipients
- Secondary APIs

**Experience in coating:**

- Granules, Beads
- Tablets
- Capsules: Hard Shell, Soft Gel

## Capsules

- Neat API in Capsule
- Powder Blends
- Multi-Particulates (Beads & Granules)
- Immediate to Modified Release
- Tablet in Capsule
- Over-Encapsulation
- Multi-API Combination Products

## Topical Dosage Forms

- Gels
- Creams
- Ointments
- Lotions

## Other Dosage Forms

- Suppositories
- Powders

# PACKAGING

Having packaging operations integrated with manufacturing services provides streamlined value for clients. CoreRx offers comprehensive primary and secondary packaging, labeling and distribution options linked with our manufacturing services to meet the needs of our clients.

## Solids

Bottles *(manual and automated lines)*
Blisters *(thermoform & coldform)*
Sachets

## Liquids

Bottles *(manual and automated lines)*
Oral Syringe Applicators

## Semi-Solids

Tubes
Jars

"We support a variety of dosage forms. From phase I – niche commercial manufacturing."

# FACILITY OVERVIEW

At CoreRx you will find a clean, professional environment with the latest in scientific resources that will provide the perfect setting to support your drug development efforts. Our facilities in Clearwater, Florida are FDA and Florida Department of Health registered as well as DEA approved (schedules II – V of controlled drugs).

Our analytical and manufacturing areas are fully GMP compliant and have an excellent inspection record.  We welcome you to visit and tour/audit our facilities.

## MYERLAKE I – 35,000 SQ. FT

- 18 GMP Manufacturing Suites
- 2 GMP Analytical Labs Supporting R&D & QC/Stability Testing
- Qualified GMP Stability Chambers
- GMP Warehouse

## MYERLAKE II – 47,000 SQ. FT.

- Office & Administrative Space
- Future GMP Warehouse Expansion
- Future Commercial Manufacturing Space

## MYERLAKE III – 47,000 SQ. FT.

- Formulation Development Laboratory with 6 R&D Manufacturing Suites
- Additional Office & Warehouse Space
- GMP Warehouse Space
- Client Dedicated Manufacturing Suite

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# WHY OUTSOURCE TO CORERX?

Whether you need specific delivery **expertise**, have outstretched your internal capacity, or are staff-limited, CoreRx consistently delivers innovative development **solutions**, on-time, and on-budget. To select the ideal development **partner**, you not only need scientific depth, but you also need a company that has the 'intangibles' that will enable them to engage well with **your team**.

- People and Expertise
- Communication
- Speed
- Quality Systems
- Flexibility



## Bring us your formulation challenge!

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